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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,438	04/13/2001	Paul G. Alchas	P-4498P2	2953

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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,438

Applicant(s)

ALCHAS ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 18, 24-35, 41, 42, 48-58, 61-65 and 71-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9, 17, 18, 24-34, 41, 42, 48-57, 61, 62 and 71-73 is/are rejected.
- 7) ☒ Claim(s) 10, 35 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 30 January 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The provisional double patenting has been obviated in view of the terminal disclaimer filed 01/30/03.

The drawing objection has been withdrawn in view of the proposed drawing filed 01/30/03.

The specification objections have been withdrawn in view of amendment filed 01/30/03.

The 112, 2nd paragraph rejections have been withdrawn in view of the amendment filed 01/30/03.

The references which were supplied with the amendment have been considered. Any references which have not been submitted will only be considered when resubmitted according to the rules.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 17-18, 26-32, 41-42, 50-55, 61, 64-65, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaisha et al. (JPO Patent No.2000-37456) in view of Dalto et al. (U.S. Patent No.5,141,496).

Gaisha et al. teach all the limitations of the claims except for the flat skin engaging surface which extends in a plane generally perpendicular to an axis of the needle cannula. Dalto et al. teach adjusting of the skin penetration depth of the needle in analogous art. Dalto et al. teach a flared portion of the limiter portion for better perpendicular guidance of the needle for penetration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the limiter portion of Gaisha et al. with a flared portion as taught by Dalto et al. for better stability when applying the injection.

With respect to claims 26, 50 and 73, see rejection above. Gaisha et al. In view of Dalton et al. is silent to the skin engaging surface having an outer diameter of 5mm. It would have been obvious to one of ordinary skill in the art to modify the size as a mere design choice because Applicant has not disclosed that modifying the outer diameter provides an advantage, is used for a particular purpose, or solves a stated problem. One ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any size since it would perform the same function equally well considering that the skin engaging surface is present to limit the depth of the needle and to give stability. Further, a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 8-9, 33-34, 56-57, 62-63, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaisha et al. (JPO Patent No.2000-37456) in view of Dalto et al. (U.S. Patent No.5,141,496) and further in view of Dragosits et al. (U.S. Patent No. 5,147,328)

See above. Gaisha et al. in view of Dalto et al. disclose the needle cannula fixedly attached to the hub portion. However, they are silent to the attachment being an epoxy curable with ultraviolet light. Dragosits et al. disclose a needle secured to the hub by various means such as mechanical connection, adhesives such as heat curable and ultraviolet curable epoxy adhesives. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle-hub attachment with an ultraviolet curable epoxy adhesive as taught by Dragosits et al. to better secure the attachment between the needle and the hub.

Claims 24-25, 48-49, 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaisha et al. (JPO Patent No.2000-37456) in view of Dalto et al. (U.S. Patent No.5,141,496) and further in view of Reich (U.S. Patent No.5,672,883).

See above. Gaisha et al. in view of Dalto et al. the invention as substantially claimed. However, they are silent to a forward and rearward cap which encloses the needle assembly there between . Reich teaches a container for storing needle assemblies with a forward and rearward cap for safe handling and transporting of needle assemblies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assembly of Gaisha et al. in view of Dalto et

al. with a rearward and forward cap as taught by Reich for safe handling of needle assemblies under government regulations.

Response to Arguments

Applicant's arguments with respect to claims 1-9,17,18,24,-34,41-42,48-57,61-65,71-73 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 10,35,58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


LoAn H. Thanh
Examiner
Art Unit 3763

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